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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,595	08/27/2003	Peilin Chen	02558B-069000US	7928

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,595

Applicant(s)

CHEN ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed May 6, 2005 is acknowledged and entered. Claims 1-5 and 7-12 are pending and under examination.
2. The rejection of claims 6-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment that deletes the term "derived".
3. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Guilbert *et al.* (*J. Immunology*, 1982, 128(6):2779-2787) is withdrawn in view of Applicant's amendment. The broadest claim is now limited to specific pathogens in claim 1 that are not discussed in the reference.
4. The rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Berneman *et al.* (*Eur. J. Immunol.* 1992, 22 :625-633) is withdrawn in view of Applicant's amendment. The broadest claim is now limited to specific pathogens in claim 1 that are not discussed in the reference.

Claim Rejections - 35 USC § 102 – Response to Applicant's Arguments

5. Claims 1-3 and 7-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Luka *et al.* (*J. Immunological Methods*, 1984, 67:145-156, herein, "Luka"). Applicant's arguments have been carefully considered, but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

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- Applicant asserts that Luka did not pool the individual sera prior to ELISA, implying that Luka's composition did not contain heterologous antibodies. Applicant stresses that heterologous antibodies according to the specification are not from the same source.
 - In response to this argument, Luka discloses a serum pool containing antibodies to all 4 antigen complexes (EBNA, VCA, EA and MA) on page 149, last paragraph. With regard to the definition of "heterologous antibodies" that are not from the same source, Applicant is arguing a product by process. The origin of the antibodies does not lend patentability to the antibodies themselves as long as they bind the indicated antigens. Even if there are structural differences between antibodies produced in one source versus another source, those differences do not affect the function of the antibodies: binding to antigens.
- Applicant argues that Luka's experiments are equivocal with regard to the pooling of the antigens into one serum composition.
 - In response to this argument, the disclosure on page 149, last paragraph, unequivocally demonstrates that a serum pool was indeed produced.

6. Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong *et al.* (US Patent 5,478,753, herein, "Wong"). This rejection was previously applied to claim 1 and 6. However, claim 6 has been cancelled, and claims 1, 4 and 5 have been amended such that their scope is limited to particular antigens. Claims 4 and 5 are drawn to compositions of claim 1 that contain ten or fifteen heterologous antibodies from the list in claim 1. With regard to the

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particular number of antibodies in claims 4 and 5, one would expect that Wong's multiple antibody calibrator composition would contain numerous antibodies to different pathogens since Wong discloses that a plurality of antibodies can be used in one assay (col. 5, lines 15-25).

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

- Applicant argues that the antibodies in Wong's calibration composition have only one antigen binding specificity.
 - In response to this argument, Applicant is arguing a limitation that is not in the claims. While the claims refer to antibodies that "specifically bind", this phrase is defined in the specification as antibodies that confirm the presence of an antigen.
Wong's antibodies meet the claim limitation as defined by the specification.
- Applicant argues that Wong's suggestion to test antibodies against multiple infectious pathogens is merely referring to the use of several different calibrators, not a single calibrator containing multiple antibodies.
 - In response to this argument, Wong explicitly teaches that one calibration composition can be used for a plurality of assays instead of requiring separate a calibrator/control composition for each assay (col. 5, lines 15-24). The Office interprets Wong's disclosure to mean that one calibrator contains multiple antibodies.

Claim Rejections - 35 USC § 103 - Response to Applicant's Arguments

7. Claim 10 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of Desmonts *et al.* (US Patent 4,612,281, herein, "Desmonts") for reasons of record. Claims 9 and 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of Desmonts as applied to claim 10 above, and further in view of Gans *et al.* (*J. Infect. Dis.*, 2001, 184:817-826, herein, "Gans"), Yi *et al.* (US Patent 6,794,153, herein, "Yi"), Krell *et al.* (US Patent 6,479,248, herein, "Krell") and Luka, for reasons of record. Claim 12 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Wong in view of Desmonts, Gans, Yi, Krell and Luka as applied to claims 9 and 11 above, and further in view of Lo *et al.* (US Patent 5,532,134, herein, "Lo"), for reasons of record. Applicant's arguments have been carefully considered but fail to persuade. Applicant's arguments are hinged on the assertion that Wong does not teach a calibrator composition comprising multiple heterologous antibodies. Applicant's substantive arguments are primarily drawn to the following:

- Applicant argues that the antibodies in Wong's calibration composition have only one antigen binding specificity.
 - In response to this argument, Applicant is arguing a limitation that is not in the claims. While the claims refer to antibodies that "specifically bind", this phrase is defined in the specification as antibodies that confirm the presence of an antigen. Wong's antibodies meet the claim limitation as defined by the specification.
- Applicant argues that Wong's suggestion to test antibodies against multiple infectious pathogens is merely referring to the use of several different calibrators, not a single calibrator containing multiple antibodies.

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- In response to this argument, Wong explicitly teaches that one calibration composition can be used for a plurality of assays instead of requiring separate a calibrator/control composition for each assay (col. 5, lines 15-24). The Office interprets Wong's disclosure to mean that one calibrator contains multiple antibodies.

Conclusion

8. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Stacy B. Chen
July 21, 2005


JAMES HOUSEL 7/25/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600